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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.:	**DRE-0055**
Inventors:	**Laurencin et al.**
Serial No.:	**09/878,641**
Filing Date:	**June 11, 2001**
Examiner:	**Chattopadhyay, Urmi**
Group Art Unit:	**3738**
Title:	**Ligament Replacement Constructs and Methods for Production and Use Thereof**

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Declaration by Dr. Frank Ko, Ph.D.

I, Frank Ko, hereby declare:

1. I am a co-inventor of the above-referenced patent application.

2. I received my B.S. Degree in Textile Engineering from the Philadelphia College of Textiles and Science and my M.S. and Ph.D degrees, also in Textile Engineering, from the Georgia Institute of Technology. I have over thirty years of experience in research and teaching of fibrous materials and structures. I am an internationally recognized expert in advanced textile structures with special expertise in braiding technology. I am the lead author of the book "Atkins & Pearce Handbook of Industrial Braiding". I have presented and published over 400 papers and talks on the subject of fibrous materials. Many of these articles are archival articles and they are related to braiding and braided structures. (e.g. Ko, F.K., "Braiding," published in Engineered Materials Handbook, Volume 1: Composites, ASM International, 1987, pp. 519-528;

and in ASM Handbook, Volume 21, Composites, ASM International, December, 2001, pp.69-77.)

3. At the outset, I would like to point out that not all 3-dimensional braids are alike. Just as in the case of vascular grafts, many of which are made of knitted structures, the distinction and/or uniqueness lies in the material and microstructural design used to make the braid. These distinctions have been recognized in the field of knitted or woven vascular grafts, as evidenced by the multitude of issued patents in this field, as rendering such grafts inventive over each other. The same rationale is applicable to the case of woven and braided fabrics being used in other devices such as ligament replacement. Simply because a device is made of a braided fabric does not make it the same nor obvious from one braid design to another. Different weave architecture and braid geometry exhibit different properties altering their utility and/or applicability for various applications.

4. I am very familiar with the prosthetic ligaments described in U.S. Patent 4,917,699 by Alan Chervitz as I assisted in the design of the braided polyester yarns. The design and fabrication of the prosthetic ligament presented in the patent was described in a report to Zimmer, Inc. in July 1984 as well in a Drexel University Masters Thesis by my student Benny Soebroto in May 1986. The title of the thesis is" Design, Fabrication and Characterization of Anterior Cruciate ligament Prostheses. A picture of the same braided ligament disclosed in the patent is shown on page 41 of Mr. Soebroto's thesis. I have attached a copy hereto as evidence of their similarity. The intended purpose for the braided polyester yarns disclosed by Chervitz was for permanent replacement of a ligament and the material concept and the design are totally different from our invention.

5. Our ligament replacement construct is designed for the regeneration of tissues and the material used was absorbable/biodegradable polymers. The fiber architecture design of our invention is completely different to that of Chervitz in that we can specially design a variable micro-structure for cell in-growth and for mechanical property. For example, in one application we specifically tailored the mid-section of the 3-D braid constructed with lower braiding angle and less interlacings for cell in growth and

the outer sections for connection and aattachment. See specifically page 12, lines 5-12 of our patent application. As demonstrated in the experiments outlined at page 7, line 9 through page 8, line 24, of our application, in the fiber structure of the 3-D braided scaffolds of our invention, fibroblasts organized along the length of the fibers and osteoblasts showed a distinctly different morphology as compared to the fibroblasts. In contrast, cells did not organize and morphology of cells types was similar in the microfiber, nonwoven mesh prepared from the same biodegradable polmeric fibers. The enhanced properties for cell growth on the 3-D scaffolds of the present invention we observed were completely unexpected and, in my opinion, were not predictable based upon what was known in the art prior to our invention.

I hereby declare that all statements herein of my own knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements were made with the knowledge that willful statements and the like so made are punishable by fine or by imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the application, any patent issuing there upon, or any patent to which this verified statement is directed.

Frank Ko

May 27, 2005

Date

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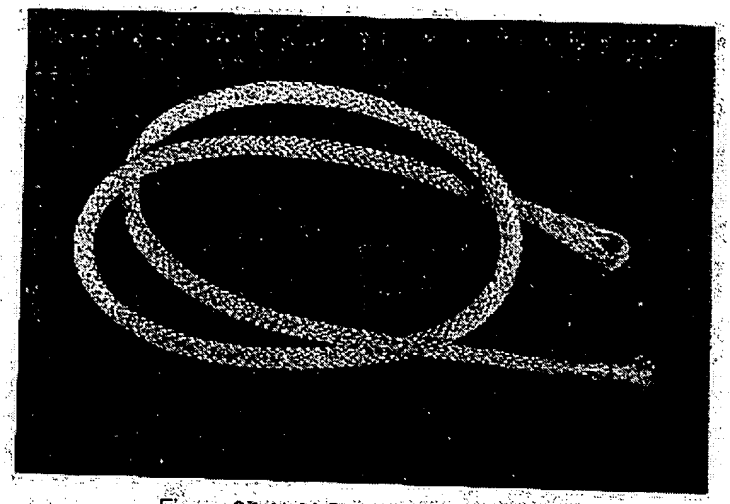

Figure 27 H-22 Tubular ACL Prosthesis.

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